REMARKS

I. Status of the Claims

Claims 17-33 are pending in this application. Claims 17 and 25 have been amended. Applicants acknowledge and appreciate that the previously imposed restriction has been withdrawn.

II. Examiner's Observation Regarding Abstract

The Examiner states that "the (one) sentence of the abstract is grammatically incorrect." (Office Action dated December 21, 2001, page 2, line 6-7.) The language of Applicants' abstract was in compliance with the *Manual of Patent Examining Procedure* ("the MPEP"), which states that phrases, which can be implied, such as "are disclosed," are to be avoided. *See* M.P.E.P. 608.01(b). Nonetheless, to advance prosecution, Applicants have amended the abstract in accordance with the Examiner's suggestion by inserting the phrase "are disclosed." The amended abstract is provided as an attachment to this Reply.

III. Rejection Under 35 U.S.C. § 112, First Paragraph

In the instant Office Action, the rejection of claims 17-24 and 32 has been maintained, and claims 25-31 and 33 are newly rejected under 35 U.S.C. § 112, first paragraph, as "containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is

FINNEGAN
HENDERSON
FARABOW
GARRETT &
DUNNER LLP

1300 I Street, NW
Washington, DC 20005
202.408.4000
Fax 202.408.4400
www.finnegan.com

most nearly connected, to make and/or use the invention."[1] (Office Action dated December 11, 2001, page 2, line 14-17.) Specifically, the Examiner alleges that "the specification is entirely devoid of guidance, and of working examples showing antibacterial activity." (Office Action dated December 11, 2001, page 4, lines 18-19.) Although it has not been articulated as such, it may be the case that the rejection is based on "lack of utility" under 35 U.S.C. § 101 and 35 U.S.C. § 112, first paragraph.[2] However, because no rejection under § 101 has been articulated by the Examiner, Applicants understand the instant rejection to only be based on the "how to use" prong of § 112, first paragraph. Applicants respectfully traverse this rejection for at least the reasons of record and the additional reasons articulated below.

"A specification disclosure which contains a teaching of the manner and process of making and using an invention ... must be taken as being in compliance with the enablement requirement of 35 U.S.C. § 112, first paragraph, unless there is a reason to doubt the objective truth of the statements contained therein... ." M.P.E.P § 2164.04. This means that in forming the rejection the Examiner should not inquire into whether

---

1 Applicants note that, notwithstanding the "make and/or use" language in the rejection, the instant Office Action and the Office Action dated June 26, 2001, focus only on the issue of "how to use" the invention. Nonetheless, to be comprehensive, Applicants in their Reply dated September 28, 2001, page 9, also addressed the issue of "how to make" the invention. But the instant Office Action does not discuss Applicants' comments regarding this issue, nor does the Examiner further explain the rejection with respect to claims 17-24 and 32 or new claims 25-31 and 33. Therefore, Applicants understand that the rejection of claims 17-33 under 35 U.S.C. § 112, first paragraph, is not based on the issue of "how to make" the invention. If Applicants' understanding is incorrect, clarification is respectfully requested.

2 The legal principle supporting a rejection under 35 U.S.C. § 112, first paragraph, which is based on "lack of utility" under 35 U.S.C. § 101, is that "if the claims in an application fail to meet the utility requirement because the invention is inoperative, they also fail to meet the enablement requirement because a person skilled in the art cannot practice the invention." *In re Swartz*, 232 F.3d 862, 863, 56 U.S.P.Q.2d 1703, 1704 (Fed. Cir. 2000). Also, "if a claimed invention does not have utility, the specification cannot enable one to use it." *In re Brana*, 51 F.3d 1560, 1566, 34 U.S.P.Q.2d 1436, 1439 (Fed. Cir. 1995).

FINNEGAN
HENDERSON
FARABOW
GARRETT &
DUNNER LLP

1300 I Street, NW
Washington, DC 20005
202.408.4000
Fax 202.408.4400
www.finnegan.com

the asserted utility is capable of being disbelieved. Rather, the Examiner should inquire into whether the asserted utility is capable of being believed. Applicants respectfully submit that the asserted utility is capable of being believed, i.e., credible.

The Examiner relies on the proposition that "structure/activity relationships of antibacterial compounds are unpredictable" (Office Action dated December 11, 2001, page 4, last line through page 5, first line) and that "even small changes in structure can lead to dramatic changes in activity, or obliteration of activity." (Office Action dated June 26, 2001, page 3, lines 7-8.) For support, the Examiner cites four references, which respectively concern (1) pyridazine N-oxides, (2) haliangicin, (3) cecropin-melittin hybrid peptides, and (4) amphipathic antimicrobial peptides. These references, however, are not relevant to the art of streptogramins. Rather, the Examiner has relied on the broader category of antimicrobials and antifungals, in general, to support his allegations of unpredictability relative to streptogramins.

It is not credible to technologically support the unpredictability of streptogramins based upon four different types of antimicrobials and antifungals. Based on this logic, the Examiner could argue that all antimicrobials and antifungals are always unpredictable. Because the cited teachings are not directly relevant to Applicants' asserted utility, the Examiner has not backed up his allegations "with acceptable evidence or reasoning" that is inconsistent with what Applicants assert in the specification. M.P.E.P. § 2164.04.

Applicants are aware that "[i]t cannot be presumed that a [compound] is 'useful' under 101, or that one of skill in the art will know 'how to use' it, simply because the compound is closely related only in a structural sense to other [compounds] known to

FINNEGAN
HENDERSON
FARABOW
GARRETT &
DUNNER LLP

1300 I Street, NW
Washington, DC 20005
202.408.4000
Fax 202.408.4400
www.finnegan.com

be useful." *In re Kirk*, 376 F.2d 936, 942, 153 U.S.P.Q. 48, 53 (C.C.P.A. 1967) (emphasis supplied). But "evidence of success in structurally similar compounds is relevant in determining whether one skilled in the art would believe an asserted utility." *In re Brana*, *supra*, n.2 at 1566, 34 U.S.P.Q.2d at 1442. Thus, the Examiner must consider two issues: (1) whether antibacterial activity is asserted in the specification, or is just presumed, and (2) if asserted, whether one of skill in the art would have a reason not to believe the asserted utility, especially in light of the fact that streptogramins, generally, exhibit antibacterial activity.

Applicants do not rely on a "presumed utility" and, thus, the instant case is different from the facts of *Kirk*. In *Kirk*, the applicants in their specification asserted the general utility of "high biological activity" and did not disclose which biological properties made the compounds useful. *Id.* at 938. The U.S. Patent and Trademark Office found the specification insufficient under § 101 and § 112, second paragraph, to support the claims. *Id.* at 937. On appeal to the Federal Circuit, the applicants/appellants argued that known specific uses of similar compounds could cure the defect, because one would expect the claimed compounds to have activity similar to the known compounds. *Id.* at 941. The court, rejecting their arguments, found that it must be disclosed in the specification that the claimed compounds had the same properties as known similar compounds. *Id.* at 942.

Unlike in *Kirk*, Applicants here do not rely on such a presumption to support the claims. Rather, Applicants set forth a specific utility in the specification—antibacterial activity. (Specification, for example, page 8, lines 12-15.) Further, Applicants disclose that the claimed streptogramin derivatives "are particularly advantageous because of

FINNEGAN
HENDERSON
FARABOW
GARRETT &
DUNNER LLP

1300 I Street, NW
Washington, DC 20005
202.408.4000
Fax 202.408.4400
www.finnegan.com

their activity, alone or combined, as well as because of their enhanced metabolic stability compared with the previously known group A derivatives." (Specification, for example, page 8, lines 15-19.) Hence, Applicants' specific teachings are consistent with the holding in *Kirk*.

Further, "when a compound or composition claim is not limited by a recited use, any enabled use that would reasonably correlate with the entire scope of that claim is sufficient to preclude a rejection for nonenablement based on how to use." M.P.E.P. § 2164.01(c) (emphasis supplied). Claims 17-33 recite no "use" elements, as these claims are simply claims to compounds (claims 17-24), claims to processes of making such compounds (claims 25-27), and claims to compositions comprising such compounds (claims 28-33). The specification provides that the claimed streptogramin derivatives can be used as antibacterials. (Specification, page 8, lines 12-19.) Further, the specification provides examples of how to administer ("how to use") the claimed streptogramin derivatives, by specifying general dosage amounts.[3] (Specification, for example, page 67, lines 26-28.) Thus, the use, antibacterial, is enabled by the dosage

3 To clarify the record, Applicants note that the Examiner has misunderstood Applicants' statement that "all of the methods needed to practice the invention were well known" set forth in Applicants' Reply dated September 28, 2001, page 12, lines 19-20 (emphasis supplied). In the instant Office Action, the Examiner questions "how can applicants argue that it was well known prior to filing that the compounds (of claim 17) were effective to inhibit growth of bacteria?" (Office Action dated December 11, 2001, page 4, lines 11-12.) Clearly, Applicants do not. All Applicants assert is that it is known in the art of streptogramins how one would administer (that is, "use") streptogramins in general, thus, one could practice/administer/use the streptogramins of the invention without undue experimentation concerning, for example, dosage amounts or routes of administration.

FINNEGAN
HENDERSON
FARABOW
GARRETT &
DUNNER LLP

1300 I Street, NW
Washington, DC 20005
202.408.4000
Fax 202.408.4400
www.finnegan.com

examples.[4] Therefore, the combination of these disclosures of the specification is sufficient to preclude the enablement rejection with respect to the compound, process, and composition claims that do not recite a specific use.

In focusing on Applicants' arguments set forth in their Amendment and Reply dated September 28, 2001,[5] the Examiner reduced these alleged arguments to one argumentative question: "If e.g., arsenic were formulated into a pill, would that cure Alzheimer's Disease?" (Office Action dated December 11, 2001, page 4, line 7.) In the Examiner's arsenic example, however, if one were to claim arsenic for curing Alzheimer's Disease, clearly there would exist a reasonable basis for doubting such an assertion because arsenic is a known toxin. With respect to the claimed compounds and compositions, however, the Examiner has not articulated, as required by both the *MPEP* and the case law, any reason for doubting Applicants' asserted antibacterial

---

4 Further, Applicants' specification discloses several routes of administration (for example, see page 65, lines 21-23) and dosages (for example, see page 67, lines 18-28). Applicants also disclose a working example of tablets comprising such dosage that could, for example, be made. (Specification, page 68, lines 3-12.) Further, Applicants disclose several references that establish that streptogramins are a recognized class of antibacterials. (Specification, page 2, line 7—page 3, line 5.) Even further, Applicants provide a disclosure of *in vivo* dosing and results (for example, see page 11, lines 20-25), low toxicity results (for example, see page 11, lines 26—page 12, line 2), and metabolic stability results (for example, see page 8, lines 12-19). In the present Office Action, neither reasoning nor support for such reasoning is provided for doubting these disclosures by Applicants.

5 First, the Examiner alleges that Applicants argued that "if an applicant discloses other compounds, structurally distinct from those being claimed, that is enough to enable 'pharmaceutical compositions,' since the mere suggestion that the claimed compounds might exhibit the same properties as the prior art compounds is sufficient to imbue the claimed compounds with the pharmacological attributes exhibited by the prior art compounds." (Office Action dated December 11, 2001, page 3, line 17 through page 4, line 2.) Second, the Examiner alleges that Applicants argued that "if an applicant has no idea whether or not a given compound exhibits a particular activity in a given biological assay, the compound in question acquires the property of exhibiting that activity in the biological assay merely by virtue of an applicant suggesting that the compound in question can be formulated into a pill or tablet and [administered] to a human subject." (Office Action dated December 11, 2001, page 4, lines 2-6 (emphasis supplied).) To clarify the record, Applicants note that Applicants have not made these arguments.

FINNEGAN
HENDERSON
FARABOW
GARRETT &
DUNNER LLP

1300 I Street, NW
Washington, DC 20005
202.408.4000
Fax 202.408.4400
www.finnegan.com

activity other than "[t]he reality of pharmacology is that one cannot predict activity merely by viewing a structure." (Office Action dated June 26, 2001, page 3, lines 4-5.) Applicants do not "merely suggest" or "predict" antibacterial activity of the claimed compounds and compositions, they specifically assert this activity in the specification.[6]

Further, Applicants disclose that the claimed compounds and compositions are in fact useful by disclosing, for example, that "[i]n vivo, on experimental infections of mice with Staphylococcus aureus IP 8203 at doses of between 25 and 150 mg/kg orally and/or subcutaneously (CD_{50}), they synergize the antimicrobial activity of pristinamycin IB of pristinamycin I_A or of quinupristin (30/70 combination)." (Specification, page 11, lines 20-25.) The disclosures set forth in Applicants' specification are objective truths, which are presumed true unless there is a reason to doubt them. Thus, the Examiner's reliance on the fact that some structurally similar compounds *might* not exhibit the disclosed utility cannot suffice as reasonable doubt. The Examiner must "articulate a satisfactory explanation for its action including a 'rational connection between the facts found and the choice made.'" *In re Lee*, 277 F.3d 1338, 1342 (Fed. Cir. 2002). The Examiner has failed to articulate such an explanation.

Additionally, the Examiner alleges without legal authority that "even if it were true that the compounds exhibited antibacterial activity *in vitro*, "undue experimentation" would be required to determine which of the claimed compounds can be used to treat even one disease caused by bacteria, to say nothing of the considerable number of diseases that one would have to test for therapeutic efficacy against." (Office Action

FINNEGAN
HENDERSON
FARABOW
GARRETT &
DUNNER LLP

1300 I Street, NW
Washington, DC 20005
202.408.4000
Fax 202.408.4400
www.finnegan.com

6 Applicants provide a disclosure of *in vivo* dosing and results (for example, see page 11, lines 20-25), low toxicity results (for example, see page 11, lines 26—page 12, line 2), and metabolic stability results (for example, see page 8, lines 12-19).

dated December 11, 2001, page 6, line 18 through page 7, line 2.) The test of enablement, however, involves an "analysis of whether a particular claim is supported by the disclosure in an application." M.P.E.P. § 2164.04 (emphasis supplied). "All questions of enablement are evaluated against the claimed subject matter [and the] focus of the examination inquiry is whether everything within the scope of the claim is enabled." M.P.E.P. § 2164.08 (emphasis supplied). Applicants do not recite any element in the claims themselves regarding treatment of any particular disease. Therefore, Applicants are not obliged to entertain the Examiner's request with respect to particular diseases.

Further, Applicants note that the Examiner's suggestion that Applicants submit "*in vitro* data that establishes the [bacterial] growth inhibitory efficacy that has been asserted" (Office Action dated June 26, 2001, page 3, lines 9-10) is misplaced. Unless and until the Examiner has established that one skilled in the art would reasonably doubt Applicants' asserted utility, Applicants are not required to provide evidence of testing or otherwise provide proof to support their asserted utility. *See* M.P.E.P. § 2164.05; *see also*, *In re Brana*, *supra*, n.2 at 1566, 34 U.S.P.Q.2d at 1441 (Fed. Cir. 1995) ("[A]pplicants should not have been required to substantiate their presumptively correct disclosure to avoid a rejection under 35 U.S.C. § 112, first paragraph," when the Office has failed to satisfy its burden of showing that one would reasonably doubt applicants' asserted utility.)

As the Examiner has failed to establish a *prima facie* case of nonenablement, Applicants respectfully request withdrawal of the rejection under § 112, first paragraph.

FINNEGAN
HENDERSON
FARABOW
GARRETT &
DUNNER LLP

1300 I Street, NW
Washington, DC 20005
202.408.4000
Fax 202.408.4400
www.finnegan.com

IV. R j ctions Under 35 U.S.C. § 112, Second Paragraph

The Examiner has rejected claims 17-33 under 35 U.S.C. § 112, second paragraph, as indefinite for failing to point out and distinctly claim the subject matter that Applicants regard as the invention.

Examiners should focus on "whether the claim meets the threshold requirements of clarity and precision, not whether more suitable language or modes of expression are available." M.P.E.P. § 2173.02 (emphasis supplied). Examiners should also allow Applicants some "latitude" in their expression and aptness of terms. *Id.* Further, in accordance with Federal Circuit precedent, Applicants are entitled to be their own lexicographers." *W.L. Gore & Assoc., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1558, 220 U.S.P.Q. 303, 316 (Fed. Cir. 1983).

Thus, if the scope of the invention can be determined from the language of the claims with a reasonable degree of certainty, then any rejection under 35 U.S.C. § 112, second paragraph, is improper. Applicants submit that their claims meet the statutory standard. Accordingly, Applicants request the withdrawal of all rejections under § 112, second paragraph.

A. Claim 17

The Examiner has rejected claim 17 for reciting the phrase "any of the foregoing," alleging that "[i]t should be made clear what is intended here." (Office Action dated December 11, 2001, page 7, lines 9-11.) If the scope of the invention can be determined from the language of the claims with a reasonable degree of certainty,

FINNEGAN
HENDERSON
FARABOW
GARRETT &
DUNNER LLP

1300 I Street, NW
Washington, DC 20005
202.408.4000
Fax 202.408.4400
www.finnegan.com

rejection is improper under 35 U.S.C. § 112, second paragraph. *See* M.P.E.P. § 2173.02. Here, the rejection is improper.

The Examiner suggests that "[t]he best option would be to create a claim that is drawn solely to mixtures." (Office Action dated December 11, 2001, page 7, lines 9-11 (emphasis supplied).) The *MPEP* directs Examiners to focus on "whether the claim meets the threshold requirements of clarity and precision, not whether more suitable language or modes of expression are available." M.P.E.P. § 2173.02 (emphasis supplied). Thus, because claim 17 and the record are both clear as to the scope of the claim, Applicants respectfully submit that this rejection is improper.

Applicants, who are entitled to be their own lexicographers, claim "[a] group A streptogramin derivative chosen from group A streptogramin derivatives of formula (I), salts thereof, and mixtures of stereoisomers of any of the foregoing... ." Thus, it is clear that the claim conveys that Applicants claim:

(1) group A streptogramin derivatives of formula (I),
(2) salts of group A streptogramin derivatives of formula (I),
(3) mixtures of stereoisomers of group A streptogramin derivatives of formula (I),
(4) mixtures of salts of stereoisomers of group A streptogramin derivatives of formula (I), and
(5) mixtures of salts of stereoisomers of group A streptogramin derivatives of formula (I) and stereoisomers of group A streptogramin derivatives of formula (I).

Applicants have claimed a group A streptogramin derivative of formula (I), for example, as a mixture of stereoisomers of group A streptogramin derivatives of formula (I). The specification provides that the methods of preparation, which may for example result in mixtures of stereoisomers of group A streptogramin derivatives of formula (I), include purification and/or separation techniques, at the option of the preparer,

FINNEGAN
HENDERSON
FARABOW
GARRETT &
DUNNER LLP

1300 I Street, NW
Washington, DC 20005
202.408.4000
Fax 202.408.4400
www.finnegan.com

depending on whether a mixture, when formed, is desired or not. (Specification, for example, page 7, lines 14-24.) Thus, because the claim, the specification, and the record are clear, Applicants respectfully request this rejection be withdrawn.

Additionally, the Examiner alleges that a contradiction is present in the last few lines of claim 17. (Office Action dated December 11, 2001, page 8, line 3.) Specifically, the Examiner questions "[i]f the carbon bearing R_1 is of the 'S' configuration, how can the 'R' configuration dominate?" (Office Action dated December 11, 2001, page 8, lines 6-7.) Applicants have amended claim 17 in the first instance of "when R" is chosen from" to provide that "said mixtures comprise at least one stereoisomer, wherein the carbon bearing said R_1 is of the R configuration, and at least one stereoisomer, wherein the carbon bearing said R_1 is of the S configuration, and wherein said R configuration is predominant." The second instance of "when R" is chosen from," however, is not similarly afflicted as alleged by the Examiner because the element "wherein said R configuration is predominant" does not exist in the second instance. Accordingly, reconsideration and withdrawal of this rejection is respectfully requested.

B. <u>The Term "Deoxopristinamycin IIA" in Claims 20-24 Is Proper</u>

The Examiner has rejected claims 20-24, alleging that the term "deoxopristinamycin IIA" may only be used if accompanied by a chemical name or structure. (Office Action dated December 11, 2001, page 8, lines 11-12.) Applicants disagree.

Applicants are entitled to be their own lexicographers. M.P.E.P. § 2173.01. Therefore, "[w]hen the specification states the meaning that a term in the claim is

FINNEGAN
HENDERSON
FARABOW
GARRETT &
DUNNER LLP

1300 I Street, NW
Washington, DC 20005
202.408.4000
Fax 202.408.4400
www.finnegan.com

intended to have, the claim is examined using that meaning, in order to achieve a complete exploration of the applicant's invention and its relation to the prior art." M.P.E.P. § 2173.05(a) (citation omitted). In the present case, Applicants have defined the terms "deoxopristinamycin IIA" and "deoxopristinamycin IIB" in the specification. For example, the specification recites that "the 16-deoxopristinamycin II_A (or II_B) nomenclature means the replacement of the ketone function at the 16-position with 2 hydrogen atoms." (Specification, page 13, lines 19-22.) Further, for example, in Example 1, which for simplicity Applicants oversimplify here, Applicants react benzylamine with pristinamycin II_B to obtain (16R)-16-Benzylamino-16-deoxopristinamycin II_B. Thus, it is clear that the ketone function of pristinamycin II_B in Example 1 is replaced with a benzylamino group. Because Applicants' claim terms are not only clear but also defined in the specification, this rejection is improper. Accordingly, Applicants respectfully request that this rejection be withdrawn.

C. R Epimer of Claim 25

The Examiner has questioned in claim 25 which chiral carbon is the term "R" epimer referring. (Office Action dated December 11, 2001, page 8, lines 13-14.) Applicants respectfully submit that it is clear that the chiral carbon at issue is the carbon bearing said R_1 as is recited in claim 17, from which claim 25 depends. However, to advance prosecution, Applicants have amended claim 25 to recite this language. Accordingly, Applicants respectfully request withdrawal of this rejection.

FINNEGAN
HENDERSON
FARABOW
GARRETT &
DUNNER LLP

1300 I Street, NW
Washington, DC 20005
202.408.4000
Fax 202.408.4400
www.finnegan.com

D. Th Examiner Has Improperly Analyzed the Definiteness of Step (a) of Claims 25 and 26 in a Vacuum

The Examiner has rejected claims 25 and 26 alleging that "[t]he claim encompasses [a] process in which the time and conditions are not effective to form a compound of formula I." (Office Action dated December 11, 2001, page 8, lines 15-17, and page 9, lines 2-3.) Applicants disagree and respectfully traverse this rejection for at least the following reasons.

Deginiteness must be analyzed in light of (1) the specification, (2) any prior art, and (3) the claim interpretation that one of ordinary skill in the art at the time the invention was made would give; definiteness must not be analyzed in a vacuum. M.P.E.P. § 2173.02. In claims 25 and 26, Applicants recite a reaction between an amine of formula (III) with a natural pristinamycin of formula (II). The Examiner has not rejected either as-claimed process as not novel or as obvious in light of the prior art. In light of the teachings of the specification of optional ways for performing such processes, no further limitations need be added to the claims.

E. The Examiner's Query Regarding Isolation Is Inappropriate

The Examiner has further rejected claims 25 and 26, alleging indefiniteness because the claims allegedly do not require isolation of the final product. (Office Action dated December 11, 2001, page 8, lines 18-19 and page 9, lines 5-6.) Applicants respectfully traverse this rejection for at least the following reasons.

Specifically, the Examiner questions "[i]f the final product is never isolated, how can it be used." (Office Action dated December 11, 2001, page 8, lines 19-20 and page

FINNEGAN
HENDERSON
FARABOW
GARRETT &
DUNNER LLP

1300 I Street, NW
Washington, DC 20005
202.408.4000
Fax 202.408.4400
www.finnegan.com

9, lines 6-7.) Applicants respectfully submit that claims 25 and 26 are each "[a] process for preparing" and do not recite use of a group A streptogramin derivative obtained. Thus, "use" is not an element of claims 25 and 26, therefore, the Examiner's question is irrelevant to the patentability these claims. Importantly, Applicants are not required to claim all steps of a process. In fact, by inserting an isolation step into the claims, the claims would tolerate infringing activity up to the point of isolation. Specifically, under the well-established case law of 35 U.S.C. § 271(g), a party outside the United States might be able to practice the invention without infringing the claims, so long as they did not "isolate" the compounds. Accordingly, Applicants intentionally drafted the claims in this manner and, thus, respectfully request withdrawal of these rejections.

F. "Capable of Generating Formaldehyde"

The Examiner has rejected claim 25, alleging that the phrase "capable of generating formaldehyde" is indefinite. (Office Action dated December 11, 2001, page 8, line 29 through page 9, line 1.) Applicants have rendered moot this rejection, however, by amending claim 25 to recite, among other things, "reacting ... with formaldehyde or a formaldehyde derivative **to generate** formaldehyde." Accordingly, Applicants respectfully request this rejection be withdrawn.

G. The Term "Group B Streptogramin Derivative" Is Sufficient

The Examiner has rejected claims 28-30, alleging that a chemical name or structural formula is required in addition to the term "group B streptogramin derivative."

FINNEGAN
HENDERSON
FARABOW
GARRETT &
DUNNER LLP

1300 I Street, NW
Washington, DC 20005
202.408.4000
Fax 202.408.4400
www.finnegan.com

(Office Action dated December 11, 2001, page 9, lines 22-24.) Applicants respectfully traverse this rejection for at least the following reasons.

Definiteness must be analyzed in light of (1) the specification, (2) any prior art, and (3) the claim interpretation that one of ordinary skill in the art at the time the invention was made would give; definiteness must not be analyzed in a vacuum. M.P.E.P. § 2173.02. In the present case, the Examiner has failed at least to consider the teachings of the specification. For example, the instant specification provides a detailed disclosure of group B streptogramins that can be used and even discloses five patents describing exemplary group B streptogramins. (Specification, page 8, line 20 through page 11, line 15.) Thus, the Examiner has failed to consider these teachings in rejecting claims 28-30 for lack of definiteness. This is improper. Respectfully, Applicants request these rejections be withdrawn.

H. The Term "Agent" Is Clear

The Examiner has rejected claim 32, alleging that the term "agent" is misleading. (Office Action dated December 11, 2001, page 9, lines 24-26.) Applicants disagree and respectfully traverse this rejection for at least the following reasons.

Specifically, without support the Examiner alleges that "the term 'agent' is normally associated with the biologically active ingredient, rather than the inactive carrier." (Office Action dated December 11, 2001, page 9, lines 24-26.) Applicants thank the Examiner for pointing out that the term "agent" might be amenable to more than one construction. Therefore, to the extent that any ambiguity was present because of the term, Applicants specifically clarify on the record that the adjective/noun

FINNEGAN
HENDERSON
FARABOW
GARRETT &
DUNNER LLP

1300 I Street, NW
Washington, DC 20005
202.408.4000
Fax 202.408.4400
www.finnegan.com

combination "active ingredient" without the adjective "active" is just "ingredient." Likewise, the noun "agent" without the adjective "active" is just "agent." Applicants recite the unmodified noun "agent" in claim 32. Thus, the term "agent" in claim 32 is now definite. Accordingly, Applicants respectfully request that this rejection be withdrawn.

I. Claim 32

The Examiner suggests that claim 32 be amended to mandate the presence of the diluent or adjuvant to distinguish the composition from the compound. (Office Action dated December 11, 2001, page 10, lines 1-6.) Applicants have amended the claim in accordance with the Examiner's suggestion. Accordingly, Applicants respectfully request withdrawal of this rejection.

J. Claims 32 and 33

The Examiner questions "what is meant by the term 'pharmaceutical composition'." (Office Action dated December 11, 2001, page 10, line 10.) As Applicants have amended the claim in accordance with the Examiner's suggestion, they respectfully request withdrawal of this rejection.

FINNEGAN
HENDERSON
FARABOW
GARRETT &
DUNNER LLP

1300 I Street, NW
Washington, DC 20005
202.408.4000
Fax 202.408.4400
www.finnegan.com

V. Conclusion

In view of the foregoing amendments and remarks, Applicants respectfully request the reconsideration and reexamination of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, L.L.P.

Dated: April 9, 2002

By: _____
Michele L. Mayberry
Reg. No. 45,644

Attachments: Appendix to Amendment
Abstract

FINNEGAN
HENDERSON
FARABOW
GARRETT &
DUNNER LLP

1300 I Street, NW
Washington, DC 20005
202.408.4000
Fax 202.408.4400
www.finnegan.com

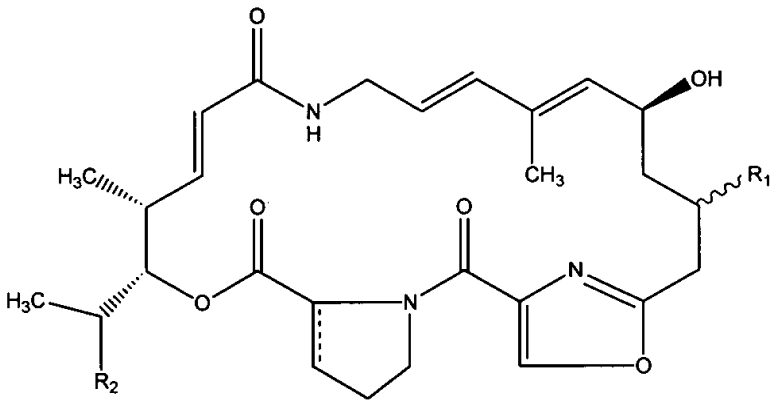
APPENDIX TO AMENDMENT OF APRIL 9, 2002

Version with Markings to Show Changes Made

IN THE CLAIMS:

Please replace claims 17 and 25 with amended claims 17 and 25, as follows:

17. (Once Amended) A group A streptogramin derivative chosen from group A streptogramin derivatives of formula (I), salts thereof, and mixtures of stereoisomers of any of the foregoing:



(I)

wherein:

- R_1 is chosen from -NR'R" groups, wherein
  - R' is chosen from a hydrogen atom and a methyl group, and
  - R" is chosen from
    - (i) a hydrogen atom,
    - (ii) alkyl groups,
    - (iii) cycloalkyl groups,
    - (iv) an allyl group,
    - (v) a propynyl group,

FINNEGAN
HENDERSON
FARABOW
GARRETT &
DUNNER LLP

1300 I Street, NW
Washington, DC 20005
202.408.4000
Fax 202.408.4400
www.finnegan.com

(vi) a benzyl group,

(vii) -OR"' groups, wherein R"' is chosen from a hydrogen atom, alkyl groups, cycloalkyl groups, an allyl group, a propynyl group, and a benzyl group, and

(viii) $-NR_3R_4$ groups, wherein

- R_3 and R_4 are each a methyl group, or
- R_3 and R_4, which are identical or different, form, together with the nitrogen atom to which they are attached, a saturated or unsaturated 4- to 5-membered heterocyclyl group, wherein one of said members, in addition to said nitrogen atom, may be an atom chosen from an oxygen atom, a sulphur atom, and a nitrogen atom,

- R_2 is chosen from a hydrogen atom, a methyl group, and an ethyl group,

- the bond ---- is a single bond or a double bond,

- unless otherwise stated, said alkyl groups are chosen from straight and branched C_1-C_6 alkyl groups,

- unless otherwise stated, said cycloalkyl groups are chosen from C_3-C_4 cycloalkyl groups,

FINNEGAN
HENDERSON
FARABOW
GARRETT &
DUNNER LLP

1300 I Street, NW
Washington, DC 20005
202.408.4000
Fax 202.408.4400
www.finnegan.com

~~- when said R" is chosen from a hydrogen atom, alkyl groups, cycloalkyl groups, an allyl group, a propynyl group, and a benzyl group, said group A streptogramin derivatives and said salts thereof are chosen such that the carbon bearing said R_4 is of the R configuration and said mixtures comprise stereoisomers, wherein the carbon bearing R_4 is of the R configuration or the S configuration and wherein said R configuration is predominant, and~~

~~- when R" is chosen from said -OR"' groups and said -NR_3R_4 groups, said group A streptogramin derivatives and said salts thereof are chosen such that the carbon bearing said R_4 is of the R configuration or the S configuration and said mixtures comprise stereoisomers, wherein the carbon bearing R_4 is of the R configuration or the S configuration.~~

- when said R" is chosen from a hydrogen atom, alkyl groups, cycloalkyl groups, an allyl group, a propynyl group, and a benzyl group:

said group A streptogramin derivatives are chosen such that the carbon bearing said R_1 is of the R configuration,

said salts are chosen such that the carbon bearing said R_1 is of the R configuration, and

said mixtures are chosen such that said mixtur s comprise at l ast on st r oisom r, wh rein th carbon b aring said R_1 is of th R

FINNEGAN
HENDERSON
FARABOW
GARRETT &
DUNNER LLP

1300 I Street, NW
Washington, DC 20005
202.408.4000
Fax 202.408.4400
www.finnegan.com

configuration, and at least one stereoisomer, wherein the carbon bearing said R_1 is of the S configuration, and wherein said R configuration is predominant, and

- when R" is chosen from said -OR"' groups and said -NR_3R_4 groups:

said group A streptogramin derivatives are chosen such that the carbon bearing said R_1 is of the R configuration or the S configuration,

said salts are chosen such that the carbon bearing said R_1 is of the R configuration or the S configuration, and

said mixtures are chosen such that said mixtures comprise at least one stereoisomer, wherein the carbon bearing said R_1 is of the R configuration, and at least one stereoisomer, wherein the carbon bearing said R_1 is of the S configuration.

25. A process for preparing a group A streptogramin derivative according to claim 17, said process comprising:

(a) preparing a group A streptogramin derivative, wherein R' is a hydrogen atom, by reacting, in the presence of a reducing agent, an amine of formula (III):

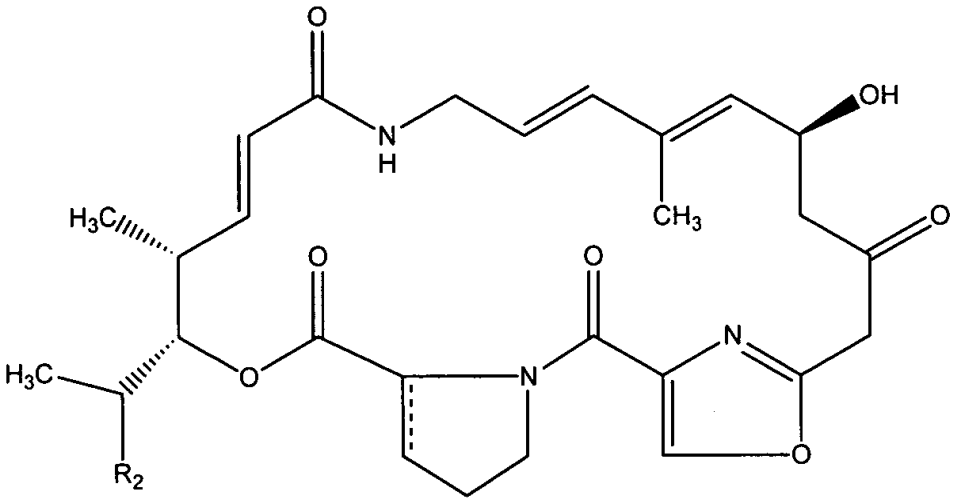
H_2N-R" (III)

wherein R" is defined as in claim 17

with a natural pristinamycin of formula (II):

FINNEGAN
HENDERSON
FARABOW
GARRETT &
DUNNER LLP

1300 I Street, NW
Washington, DC 20005
202.408.4000
Fax 202.408.4400
www.finnegan.com



(II)

wherein R_2 is defined as in claim 17,

(b) optionally reacting said group A streptogramin derivative of formula (I), wherein R' is a hydrogen atom, with formaldehyde or a formaldehyde derivative ~~capable of generating~~ **to generate** formaldehyde in situ to form a second intermediate compound, and then reacting said second intermediate compound with a reducing agent to form a group A streptogramin derivative, wherein R' is a methyl group, and

(c) optionally converting said group A streptogramin derivative of formula (I), prepared by (a) or (b) above, to a salt ~~and/or separating its R-epimer~~ **and separating said salt, wherein the carbon bearing said R_1 is of the R configuration, or optionally separating said group A streptogramin derivative, wherein the carbon bearing said R_1 is of the R configuration**.

FINNEGAN
HENDERSON
FARABOW
GARRETT &
DUNNER LLP

1300 I Street, NW
Washington, DC 20005
202.408.4000
Fax 202.408.4400
www.finnegan.com